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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/939,905	09/29/1997	MARK GIJZEN	76.105	4378

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EXAMINER	
ZHOU, SHUBO	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 01/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 08/939,905	**Applicant(s)** GIJZEN, MARK	
	Examiner Shubo (Joe) Zhou	**Art Unit** 1631	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 December 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☒ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See continuation sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *1,3,4,8-12,14,15,17,19,21,23,25 and 27*.
   Claim(s) objected to: _____.
   Claim(s) rejected: *7, 16, 18, 20, 22, 24, 26, 28-29, 36-39*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See continuation sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 3(a) and 3(b):

The amendments of changing "at least 19 contiguous nucleotides" to "at least 20 contiguous nucleotides" in claims 36-39 require new consideration. Further, this new limitation "at least 20 contiguous nucleotides" of nucleotides 1524-1610 of SEQ ID NO:2 is considered new matter because it is not adequately described in the specification. Applicants assert that support for the limitaiton can be found in the specification on page 33, line 10, through page 34, line 4, etc. However, consideration of said pages reveals that no "at least 20 contiguous nucleotides" of nucleotides 1524-1610 of SEQ ID NO:2 or its equivalent is adequately disclosed therein.

Continuation of 11:

With regard to the rejection of claims 36-39 under 35 USC 112, first paragraph (written description rejection), applicants argue that the claims are drawn to a method that may be used to differentiate EpEp and epep genotypes that involve sequence comparisons between the genotypes, and support for this can be found on pages 10, line 16to page 12 line 22, etc. This is not found persuasive because the argument is not about the reason for the rejection: The limitation "at least 19 contiguous nucleotides ... SEQ ID NO:2" introduced into the claims is new matter. The limitation "at least 19 contiguous nucleotides ... SEQ ID NO:2" or its equivalent is not found to be adequately disclosed on pages 10 through 12, etc.

With regard to the rejection of claims 7, 16, 18, 20, 22, 24, 26, and 28-29 under 35 USC 112, first paragraph (scope of enablement rejection), applicants argue that there is description in the specification for sequences having transcriptional regulatory activity, and further argue by citing "Example 9" of the "Synopsis of Application of Written Description" that the high stringency conditions used for hybridization would allow for production of sturcturally similar DNAs. This is not found persuasive because firstly, this rejection is not a written description rejection, but rather a scope of enablement rejection. Secondly, assuming arguendo that the conditions for hybridization did allow for production of structurally similar DNAs, this meant that the sequences obtained from hybridization would still not be identical to the probe sequence. Given that it would have been known in the art that even a single mutation or substitution or mismatch would be able to abolish any activity of a nucleic acid molecule, it would require further experimentation to determine what sequence, if any, obtained from hybridization would have transcriptional regulatory activity. Further, as set forth in the rejection mailed 3/31/05, transcriptional regulatory activity also includes activity of operator, regulator, suppressor and/or enhancers, etc., it would require undue experimentation for a practioner in the art to practice the invention, i.e. to find such transcriptional activity of sequences, if any, from the nucleic acids obtained from hybridization.

Ardin H. Marschel 1/13/06

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SUPERVISORY PATENT EXAMINER